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C. 510(K) SUMMARY

The 510(k) summary for the CARTO XP V8 Mapping System is provided below.

510(k) Summary for the CARTO™ XP V8 EP Navigation System

510(k) Notification Submitted by:	Biosense Webster, Inc. 3333 Diamond Canyon Rd. Diamond Bar, CA 91765 USA Phone: +1-800-729-9010 Fax: +1-909-839-8804
Contact Person:	Diana Thorson Project Manager, Regulatory Affairs
Proprietary Device Name:	CARTO™ XP EP Navigation System
Classification Name:	Programmable diagnostic computer (per 21 CFR 870.1425)
Common Device Name:	Cardiac mapping system
Predicate Devices:	A. CARTO™ XP QwikMap EP Navigation System B. Siemens Medical System *singo* Multimodality Workstation
Manufacturer:	Biosense Webster (Israel) Ltd. POB 2009 Tirat HaCarmel, 39120 Israel

Indications For Use

The CARTO™ XP EP Navigation System is intended to acquire real time catheter based cardiac electrophysiogical maps in patients who are eligible for a conventional electrophysiological study. The CARTO™ XP EP Navigation System is restricted for use by licensed medical practitioner who participated in a CARTO™ training course. There are no special contraindications when using the CARTO™ XP EP Navigation System.

General Device Description

The CARTO™ XP EP Navigation system is designed to acquire, analyze, and display electro-anatomical maps of the human heart. The maps are reconstructed using the combination of information gathered from the integration of intracardiac electrograms with their respective endocardial locations. Maps may be displayed as electrical activation maps, electrical propagation maps, electrical potential maps, and chamber geometry maps. The acquired patient signals, including body surface ECG and intracardiac electrograms may also be displayed in real time on the display screen.

The CARTOMERGE module provides for the import, processing, visualization and analysis of pre-acquired cardiac images, superimposed to the CARTO XP EP maps. The CARTOMERGE supports import of Computed Tomography (CT) and Magnetic Resonance (MRI) images in DICOM format.

The CARTO™ XP EP Navigation System complies with the following safety standards:
UL 2601-1:97/CSA C22.2 NO.601.1
IEC 60601-2-25:93 and Al(99)
IEC 60601-2-27:94

The non-clinical bench and animal testing show that the device is as safe and as effective as the previously marketed devices to which it is being compared and does not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 1 2005

Biosense Webster, Inc.
c/o Ms. Diana Thorson
Project Manager, Regulatory Affairs
3333 Diamond Canyon Road
Diamond Bar, CA 91765

Re: K042999
Trade Name: CARTO™ EP Navigation System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: II (two)
Product Code: DQK
Dated: January 31, 2005
Received: February 03, 2005

Dear Ms. Thorson:

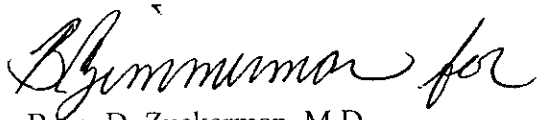
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

D. INDICATIONS FOR USE STATEMENT

510(k) No (if known): K042999

Device Name: CARTO™ EP Navigation System

Indication for Use:

The intended use of the CARTO™ XP mapping system is catheter-based atrial and ventricular mapping.

The CARTO™ XP mapping system allows real-time display of cardiac maps in a number of different formats. Maps may be displayed as cardiac electrical activation maps, cardiac electrical propagation maps, cardiac electrical potential maps, and cardiac chamber geometry maps. The acquired patient signals, including body surface ECG and intracardiac electrograms may also be displayed in real time on the display screen.

The intended use of the modified device is the same as for Predicate Device A cleared under 510 (k) Number K020863. The indications for use have been expanded to include the CARTOMERGE™ capability to import, register and merge CT or MRI structural images with CARTO maps physiological information and real time catheter navigation.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K042999